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# Quality Management in BCRC

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# *Food Industry Research and Development Institute (FIRDI)* *(Hsinchu city, Taiwan) Since 1965*



# Biological Materials Holding by BCRC

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## Microbial Resources

**(Total > 24,000 strains)**

**Bacteria**

**Fungi**

**Actinomycetes**

**Mushrooms**

**Hosts**

**Phages**

**Yeasts**

## Patent Deposit

**(Total > 1,700 strains)**



## Cell Resources

**(Total > 18,000 cells)**

**Cell Bank**

**Stem Cell Bank**

**Taiwanese Genetic Cell Bank**

## Gene Resources

**(Total > 927,000 clones)**

**Plasmids**

**Clones**

**Genetic Libraries**

# Quality Management System

## ◆ ISO 9001 (since 2001)



## ◆ ISO 17025 (since 2007)



# ISO 9001: Implementing Activity

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- ◆ Depository of Patent-Related Biological Materials;
- ◆ Contract Microbial Identifications & Tests;
- ◆ Cultivation & Preservation of Animal Cells;
- ◆ Culture Collection, Preservation & Distribution;
- ◆ Collection, Preservation and Distribution of Genomic and Complementary DNA Libraries.



# ISO 17025: Accredited Scope

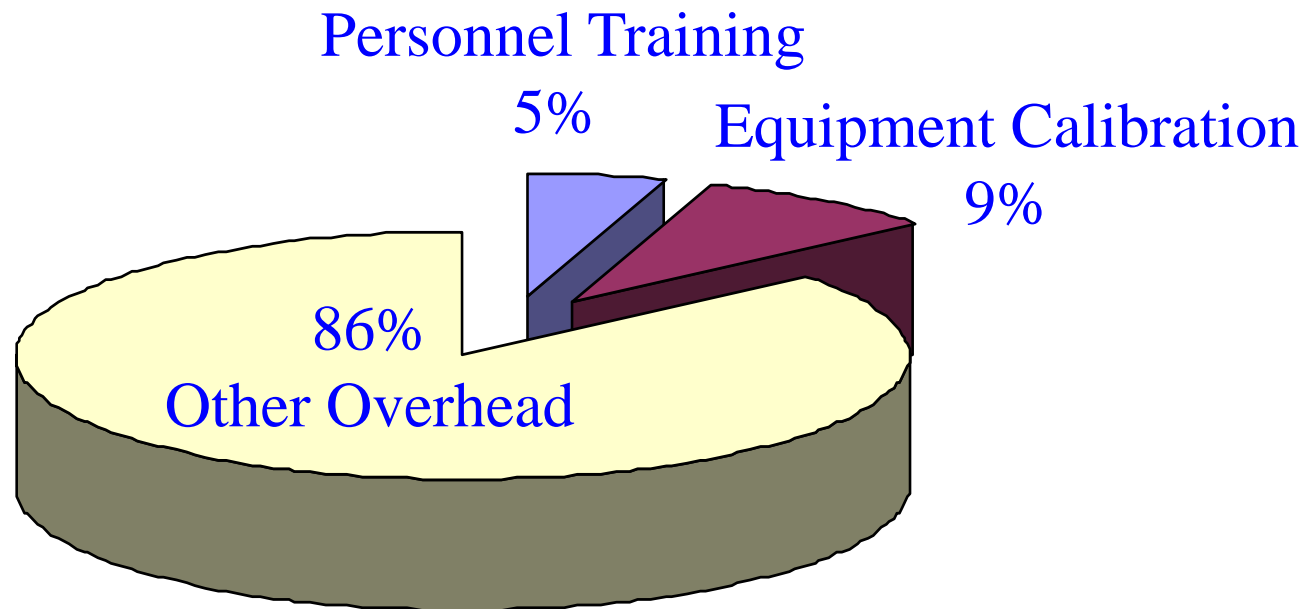
Testing method	Testing Field	Accredited Item
Antibiotic Test (JIS Z 2801)	-Metals and Alloys Products	-Metal
	-Cements, Clays, Ceramics and Related Materials	-Glass
	-Cements, Clays, Ceramics and Related Materials	-Ceramics
	-Coatings, Printing Ink and Pigments	-Paint
	-Polymer and Composite Materials	-Plastic
Ames Test	-Foods	-Solid food, liquid food, health food
	-Drugs, Chinese Herbal Preparations and Pharmaceuticals	-Chinese herbal medicine
	-Chemical Reagent	-Chemicals
<i>Legionella</i> Test	-Environmental Protection	-Water Sample

# BPG is specially tailored for BRCs

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- ◆ Organizational requirement
  - Long-term sustainability, Biosafety, etc.
- ◆ Preparation of media and reagents
- ◆ Accession and supply
- ◆ Preservation and maintenance
- ◆ Biosecurity
- ◆ Informatics
- ◆ Compliance with law

# Implementing BPG will be costly



The maintenance cost directly associated with the ISO system in 2009

- **6.4%** of the total cost in BCRC (excluding the technology development cost).
- Maintenance cost only, not including system introducing cost, or the cost already existed in BCRC before the system.
- Including management, auditing, monitoring and measurement, documentation, calibration, and training costs exclusive for ISO system.



# BPG is complementary to ISO system

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- ◆ “The quality management system requirements ... are complementary to requirements for products.”  
(cited from Introduction, ISO 9001:2008)
- ◆ BPG defines “requirements for BRCs”.

# Integration BPG into ISO system is recommended

- ◆ Establishing ISO quality objectives with BPG requirements step-by-step.

For example,



Thank you for your attention

